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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,747	02/13/2002	Susana Salceda	DEX-0315	1833

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LICATLA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053

EXAMINER	
WILDER, CYNTHIA B	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,747	SALCEDA ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6,11-14,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-10 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election with traverse of Group 1, claims 1-5, 7-10, 15 and SEQ ID NO: 8 encoding SEQ ID NO: 82 submitted on August 25, 2003 is acknowledged. The traversal is on the ground(s) that MPEP 803 provides two criteria which must be met for a restriction requirement to be proper. The first is that the inventions be independent or distinct and the second is that there would be a serious burden on the Examiner if the restriction is not required. Applicant contends that a search of prior art relating to an elected nucleic acid, polypeptide or antibody would also reveal any reference teaching uses for the nucleic acid, polypeptide or antibody. Applicant contends that searching all of the claims at least when limited to elected nucleic acids or polypeptides is overlapping and would not place an undue burden on the Examiner if the restriction is not made. Applicant contends that since the restriction requirement does not meet both the criteria as set forth in MPEP 803 to be proper, reconsideration and withdrawal of this restriction requirement is respectfully requested. Applicant states that in addition, with respect to the election of a single sequence, MPEP 803.04 clearly states that a reasonable number of nucleotide sequences, normally ten sequences, can be claimed in a single application. Accordingly, withdrawal of this sequence election requirement and consideration to included a more reasonable number of at least 10 sequences in accordance with MPEP 803.04 is also respectfully requested. However, it is maintained that the inventions are not only distinct one from the other but that undue burden would be required to examine the claims of Groups I along with the claims of Groups II through VII as evidenced by the fact that the claims of Groups I through VII have acquired a separate status in the art as recognized by their different classifications, as recognized by their divergent subject matter and because the searches of the

different inventions are not coextensive. Specifically, a search of the subject matter of invention I is not necessarily required for or combined with the subject matter of the claims of Groups II through VII. Additionally, a search of the different inventions I through VII would result in search of non-overlapping subject matters.

With respect to Applicant arguments that the restriction requirement is improper because MPEP states that a reasonable number of nucleotides sequences, normally ten sequences, can be claimed in a single application. It is noted that MPEP 803.04 specifically states that "It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, **up to ten independent and distinct nucleotide sequences** will be examined in a single application without restriction." (see MEP 803.04). The limitation "up to ten independent and distinct nucleotide sequences" is interpreted by the Office as being equivalent to "**one**" independent and distinct nucleotide sequence. Likewise, because the different sequences of the instant invention are structurally and chemically distinct one from the other, an undue search burden would be required of the examiner. Accordingly a restriction between the different sequences is also deemed proper. The requirement is still deemed proper and is therefore made FINAL. Claims 1-17 are pending in the instant invention. Claims 6, 11-14, 16 and 17 are withdrawn from consideration. Claims 1-5, 7-10, 15 and SEQ ID NO: 8 encoding SEQ ID NO: 82 are addressed below.

The examiner has required restriction between product and process claims. Where applicant elects claims direct to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all of the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP

821.04. **Process claims that depend from or otherwise include all of the limitations of the patentable product** will be entered as a matter of right if the amendment is present prior or final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFRT 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. 103(b)", 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in loss of the right to rejoinder.**

Further, not that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Specification

2. The disclosure is objected to because of the following informalities:

(a) The use of the trademark "Green-5-UTP" at page 36, line 9, "FastTag" at page 37, line 5, "ExpressSF" at page 46, line 13 and page 58, line 1, "Calphos" and Effectene" at page 60, lines 1 and 7 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

(b) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at pages 53 at line 33, page 54 at lines 4, 6 and 8, page 59 at line 7 and page 60 at line 9. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code by deleting "http://". See MPEP § 608.01.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claims 1-5, 7-10 and 15 are rejected under 35 USC 101 because the claimed invention lacks patentable utility. The instant application does not disclose a specific, substantial, and credible utility for the nucleic acid sequence mentioned in the claims. The instant application does not disclose a connection between presence or expression of SEQ ID NO: 8 and ovarian cancer. For example, none of he tables between 114 and 127 shows such

nexus. The demonstration of expression of a sequence in a specific tissue type cannot be translated to mean that that sequence is necessarily a marker for cancer in that tissue. In addition, the application does not disclose or teach the meaning or significance of any particular assay for expression of SEQ ID NO: 8. Thus, the instant application does not disclose a specific, substantial, and credible utility for SEQ ID 8, nor is there a readily apparent utility under 35 USC 1012 for SEQ ID NO: 8.

Claim Rejections - 35 USC § 112 first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-10 and 15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible or an asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make and/or use the claimed invention. The discussion in the rejection under 35 USC 101 is incorporated here.

Claim Rejections - 35 USC § 112 first paragraph: Deposit

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-5, 7-10 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it most nearly connected, to make and/or used the invention. The specification lacks deposit information for the deposit of the plasmid deposited with ATCC as discussed at page 115 through 118 of the specification (Example 1a) for SEQ ID NO 8. While the specification provides extensive information for one of skill in the art to produce a cDNA sequence, reproduction of the identical cDNA insert of the plasmid as recited in Example 1a is an extremely unpredictable event. Applicant's cited support and referral to the deposit of plasmid with the ATCC at pages 115-118 of the specification is not considered sufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met for the claimed deposit. If a deposit is made under the terms of the Budapest Treaty, than an affidavit or declaration by Applicant(s), or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, than in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public for the enforceable life of the patent;

(d) a test of the viability of the biological material at the time of the deposit (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each member State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required along with a statement verifying whether or not the deposit was made under the Budapest Treaty.

Claim Rejections - 35 USC § 112: Lack of adequate written description

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5, 7-10 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-5, 7-10 and 15 are drawn to a an isolated nucleic acid molecule comprising (a) a nucleic acid molecule comprising a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO: 77-129; (b) a nucleic acid molecule comprising a nucleic acid sequence selected from SEQ ID NO: 1-76; (c) a nucleic acid molecule that selectively

hybridizes to the nucleic acid molecule (a) or (b); or (d) a nuclei acid molecule having at least 60" sequence identity to the nucleic acid molecule of (a) or (b). The claims are also drawn to vector, host cells, and kit comprising said nucleic acids. The recitation of "a nucleic acid molecule that selectively hybridizes to the nucleic acid molecule of (a) or (b) and a nucleic acid molecule having at least 60% sequence identity to the nucleic acid molecule of (a) or (b) encompasses a large genus of nucleic acid species not adequately described or disclosed. Specifically, the specification nor examples beginning at page 113 describe or disclose the numerous nucleic acid molecules which hybridizes to or is capable of hybridizing with the sequences of SEQ ID NO: 8. Likewise, the specification does not describe or disclose any functionality of the undisclosed nucleic acid molecules associates with a sequence having only at least 60% identity to SEQ ID NO: 8. Thus, the scope of the claims include numerous structural variants thereof, and the genus is highly variable because a significant number of structural differences between genus members is permitted. Likewise the specification or claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 8 alone is insufficient to describe the genus. A representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to

one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus applicant was not in possession of the claimed genus.

Claim Rejections - 35 USC § 112 second paragraph: Indefiniteness

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-5 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1-5 and 15 are vague and indefinite because they claim more than was elected.

(b) Claims 1-5 are vague and indefinite at the recitation of "selectively hybridizes" in claim 1 because the term as not been clearly defined at pages 15-17 of the specification. The term is a relative one and no frame of reference is given. Additionally the determination or characterization of selective hybridization requires knowledge or disclosure of potential hybridization targets and/or probes in the reaction mixture. None is given or mention; thus the claim is vague, indefinite and incomplete.

(c) Claim 15 is vague and indefinite because the "means" for determining the presence of the nucleic acid as required by the kit are not clearly defined in the specification or claims. Thus one cannot clearly determine what is required in the kit.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-5, 7-10 and 15 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Hillman et al (US 6,135,941 (patent date: October 24, 2000) and (filing date: March 27, 1998). Regarding claims 1-5, 7-10 and 15, Hillman et al. discloses a nucleic acid sequence capable of hybridizing with the sequence of SEQ ID NO: 8, said nucleic acid sequence having 93.3 % similarity with the sequence of SEQ ID NO: 8 (see copy of the alignment attached to the reference). Hillman et al also discloses the used of nucleic acids for cancer detection and means of doing so(see col. 27, lines 7 through col. 28, line 22 and col. 25, lines 19-27). Hillman et al disclose the production of recombinant proteins, expression vectors and host cells (claims 5-9). Thus the compositions and methods of the reference are embraced by the claims.

Conclusion

12. No claims are allowed. However, the full sequence of SEQ ID NO: 8 is free of the prior art.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. After January 14, 2003, the examiner's may be reached at (571) 272-0791. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

CYNTHIA WILDER
PATENT EXAMINER

Cynthia B. Wilder, Ph.D.
Art Unit 1637

November 20, 2003